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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,749	01/28/2004	Ira Tabas	60921-A/JPW/AJM/MVM	6443
7590 John P. White, Esq. Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER BUNNER, BRIDGET E	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/767,749

Applicant(s)

TABAS, IRA

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,27,50,53,62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) 65-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,27,50,53 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2,27,50,53,62 and 65-67 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/23/04 and 1/28/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/23/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 16 August 2007 has been entered in full. Claims 1, 2, 27, 50, 53, 62 are amended. Claims 65-67 are added. Claims 3-26, 28-49, 51-52, 54-61, and 63-64 are cancelled.

Claims 65-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 November 2006. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Claims 1, 2, 27, 50, 53, 62 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

1. The objections to the specification at pages 2-3 of the previous Office Action (13 February 2007) are *withdrawn* in view of the amended specification (16 August 2007).
2. The objections to claims 13, 14, 51, 52, and 54-61 at page 3 of the previous Office Action (13 February 2007) are *withdrawn* in view of the cancelled claims (16 August 2007).
3. The rejection of claims 1-2, 13-14, and 27 under 35 U.S.C. § 112, first paragraph (scope of enablement), as set forth at pages 3-8 of the previous Office Action (13 February 2007) is *withdrawn* in view of the cancelled claims (16 August 2007) and after further consideration of the prior art.

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4. The rejection of claims 1-2, 13-14, and 27 under 35 U.S.C. § 112, first paragraph (written description) as set forth at pages 8-10 of the previous Office Action (13 February 2007) is *withdrawn* in view of the amended and cancelled claims (16 August 2007).
5. The rejections of claims 27 and 62-64 under 35 U.S.C. § 112, second paragraph as set forth at pages 10-11 of the previous Office Action (13 February 2007) are *withdrawn* in view of the amended and cancelled claims (16 August 2007).
6. The rejection of claims 1-2, 13-14, and 27 under 35 U.S.C. § 102(b) as set forth at page 11 of the previous Office Action (13 February 2007) is *withdrawn* in view of the amended and cancelled claims (16 August 2007).

#### ***Information Disclosure Statement***

The information disclosure statement filed on 23 August 2007 has been considered by the Examiner. It is noted that several of the references have been crossed off because they were cited in duplicate or were listed on the PTO-892 mailed with the previous Office Action of 13 February 2007.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1-2, 27, 50, 53, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. (Cardiovascular Pathol 9(6): 317-322, 2000) in view of Kellner-Weibel et al. (Arterioscler Thromb Vasc Biol 18: 423-431, 1998).

Houser et al. teach that hypercholesterolemic male New Zealand white rabbits are administered doses of progesterone (pg 318, col 1). Houser et al. disclose that feeding the rabbits a C-enriched diet for a relatively short period of time results in advanced aortic atherosclerotic plaques that contain foam cell macrophages and smooth muscle cells histologically similar to human atherosclerosis (pg 320, col 1, first paragraph). Houser et al. teach that high doses of 17-hydroxyprogesterone are significantly associated with less aortic plaque load than controls (abstract; pg 320, col 1-2; page 317, bottom of column 2). Additionally, since Houser et al. utilize a rabbit model for atherosclerosis, the progesterone utilized in Houser et al. inherently performs the function required by the claims of the instant case, absent evidence to the contrary (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)). (It is noted that it is well known in the prior art that progesterone is an amphiphilic compound and that it inhibits intracellular transport of cholesterol (see for example, Lange et al. 1994; Mazzone et al. 1995; Aikawa et al. 1994).

Houser et al. does not teach the administration of an amphipathic/amphiphilic amine.

Kellner-Weibel et al. teach that the amphipathic amine, U18666A, modulates intracellular trafficking of cholesterol (see abstract). Kellner-Weibel et al. also disclose that the toxic effect of free cholesterol can be eliminated or moderated by the treatment of macrophages with U18666A in a model foam cell culture system (page 428, column 2, first full paragraph; page 429, last paragraph in column 2). Specifically, the addition of U18666A to acyl coenzyme

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A: cholesterol acetyltransferase (ACAT)-inhibited macrophages appeared to delay or suppress cell death (page 426, bottom of column 2; page 427, Table). Kellner-Weibel et al. teach that monolayers cotreated with U18666A and an ACAT inhibitor and the cells macrophages treated with U18666A alone had efflux kinetics similar to the control cells (page 427, top of column 2; Figure 6). Additionally, macrophages treated with an ACAT inhibitor and U18666A had only a few intracellular free cholesterol crystals (page 427, bottom of column 2). Kellner-Weibel et al. add that no crystals were evident in control cells or cells treated with U18666A alone (page 428, top of column 1). Kellner-Weibel et al. also state that other compounds (such as progesterone) that have characteristics similar to that of U18666A may play a role in maintaining cell integrity in the face of excess free cholesterol (page 430, column 1, last sentence).

Thus, because both Houser et al. and Kellner-Weibel et al. teach amphiphilic/amphipathic compounds that inhibit the intracellular transport of cholesterol, it would have been obvious to one skilled in the art to substitute the utilization of U18666A for progesterone to achieve the predictable result of reducing aortic plaque load, inhibiting macrophage cell death, and inhibiting atherosclerotic lesional complications.

***Conclusion***

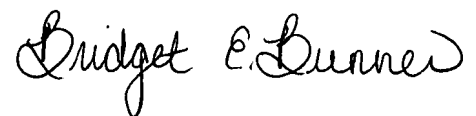
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
23 October 2007



BRIDGET E. BUNNER  
PRIMARY EXAMINER